

### **REMARKS/ARGUMENTS**

Claims 14 and 23 have been revised to include “spelled out” version of abbreviations in each claim. Claims 25, 27, 29, 30, and 31 have been revised to correct clerical errors in claim dependency.

The Claims have also been revised to feature an antiestrogen agent selected from tamoxifen and letrozole. This change has been made for business reasons rather than any alleged issue of patentability, and Applicants expressly reserve the right to re-present, in a continuing application, claims directed to subject matter no longer encompassed by the revised claims. No new matter has been introduced, and entry of the above claims is respectfully requested.

#### **Priority**

Without acquiescence to the allegations regarding support from prior U.S. applications 60/504,087 and 10/727,100, Applicants acknowledge the indication that for prior art purposes, the February 6, 2004 filing date of the instant application has been used by the Office. Applicants expressly reserve their right to withdraw the claim of priority to one or both of the above-listed applications.

#### **Objections to the Claims**

Claims 14 and 23 were objected to based upon informalities due to the use of abbreviations in both claims and the phrase “to determine outcome of a human subject” in the preamble of Claim 14.

Claims 14 and 23 have been revised to include the “spelled out” version of the two abbreviations on initial use. Applicants respectfully decline to make any changes with respect to the preamble of Claim 14 because no change appears to be necessary, especially in light of the body of the claim, which states in part “as indicating an outcome comprising cancer

that is non-responsive....” Applicant respectfully submit that in light of this content in the body of the claim, no change is needed.

Reconsideration and withdrawal of the objections is respectfully requested.

*Alleged Rejections Under 35 U.S.C. § 1.112, second paragraph*

Claims 25, 27-31, 69, and 71 were rejected as allegedly indefinite due to dependency from canceled Claim 24. Applicants have corrected a clerical error in claim dependency and this rejection may be properly withdrawn.

*Alleged Rejections Under 35 U.S.C. § 1.112, first paragraph*

Claims 14, 16, 18-23, 25, 27-31, 52-55, 62, 63, 69, and 71-73 were rejected under the above-listed statute as allegedly containing “new matter.” Applicants have reviewed the statement of the rejection and respectfully submit that no *prima facie* case has been presented.

The focus of the instant rejection appears to be on page 14 of the Action mailed October 13, 2010, where the Office remarks that

the zero point on the

Y-axis of Figure 7 of the '100 application represents the mean ratio of HoxB13:IL17BR mRNA expression levels, it does not appear from the disclosure that the mean ratio was used as a comparison point as required by the claims.

The above-quoted text recognizes that the value of “0” on the vertical axis of Figure 7 represents the mean or average ratio of expression levels. Applicants respectfully submit that this recognition should be used in combination with consideration of both literal and descriptive support in the description and Figure 7.

Because of the data plotted in Figure 7 provides descriptive support for the claims because inherently, the data was compared to the value of “0” in the Figure. The mere instance

of an exemplary “-0.22” cut point in Example 4 and Figure 7 does not alter the fact that Figure 7 presents, without ambiguity or doubt, vertical axis values of -2, 0, 2, 4, and 6 in the upper left panel and vertical axis values of -2, -1, 0, 1, 2, and 3 in the lower left panel. It is also without doubt that the vertical axis values of -2, 0, and 2 are in common between the two panels.

The data in each of these panels was clearly plotted in relation to these three common values, and this provides descriptive support for the claims, which simply feature the value of “0”, which is the average ratio as recognized by the above.

In light of the clear support provided by the above discussion, Applicants respectfully submit that there is no issue of “new matter” regarding a mean (or average) ratio as featured in the claims. So Applicants respectfully submit that no *prima facie* case of “new matter” is present, and this rejection may be properly withdrawn.

Claims 14, 16, 18-23, 25, 27-31, 52-55, 62, 63, 69, and 72 were rejected under the above-listed statute as allegedly not enabled for the scope beyond letrozole. Without acquiescence to this rejection, Applicants have revised the claims to feature either tamoxifen or letrozole. Applicants point out that the tamoxifen subject matter is the subject of the patented claims in U.S. Patent 7,504,214.

Accordingly, the instant rejection may be properly withdrawn.

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

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If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 425-681-1833.

Respectfully submitted,

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